REMARKS

Claims 1-20 were pending in the above-referenced patent application (this "Application").

Claims 1-3, 5, 6, 10, 11, 13-15, 17, 18 and 20 were elected *with traverse* in this Application.

Claims 4, 7-9, 12, 16 and 19 were withdrawn from consideration *without prejudice* in this Application.

Claims 1-3, 5, 6, 10, 11, 13-15, 17, 18 and 20 stand rejected in this Application.

Claims 1-3, 5, 6, 10, 11, 13-15, 17, 18 and 20 remain in this Application.

In the Office Action, the Examiner objected to Claim 15 and suggested modification. The undersigned believes respectfully that the Examiner misread the claim, and it is in fact in condition for allowance.

In the Office Action, the Examiner rejected Claims 1-3, 5 and 6 under 35 U.S.C. 102(b) as anticipated by United States Patent No. 5,879,319 (hereinafter, "the '319 Patent"), as the Examiner asserts that the reference discloses an ocular prosthesis having all the claimed features set forth in the above-identified claims.

Section 102, in pertinent part, provides that a "person shall be entitled to a patent unless . . . (b) the invention was

patented or described in a printed publication in this or another country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." It is axiomatic that anticipation of a claim under §102(b) can be found only if the prior art reference discloses every element of the claim. *See, In re King*, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986) (citing with approval, *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984)).

Independent Claim 1 reads as follows:

> 1. A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising:
> a central body portion having a first end and a second end, at least one end portion extending from either said first or second end of said central body portion, said at least one end portion having a width greater than said central body portion,
> said central body portion having a bottom surface which is curved along a long axis of said prosthesis,
> wherein a curvature of said bottom surface is greater than a curvature of an innermost surface of a scleral pocket or tunnel into which said prosthesis is to be implanted,
> wherein said prosthesis is adapted to expand a portion of a sclera proximate to the scleral pocket or tunnel when said prosthesis is inserted within said scleral pocket or tunnel, and
> wherein said end portion is adapted to rest on a portion of said sclera outside said scleral pocket or tunnel when said prosthesis is inserted within said scleral pocket or tunnel and to inhibit rotation of said prosthesis within said scleral pocket or tunnel [emphasis added].

A determination of anticipation, with respect to Claim 1, requires that each feature claimed be described in sufficient detail in the '319 Patent to enable one of ordinary skill in the art to make and practice the claimed invention.

The '319 Patent is directed to and teaches a "sclerotomy implant intended to be set in place in the sclera of the eye in order to provide for a continuous flow of aqueous humor through the trabecula for the treatment of a glaucoma." *See*, ABSTRACT of the '319 Patent. The implant of the '319 Patent comprises "an intrascleral portion (1) and a sub-conjuctival portion (5), the latter being adapted to come out of the sclera and penetrate under the conjunctiva. . . . [and further] comprises at least one continuous flow passage from its trabecular extremity . . . applied against the trabecula up to its external extremity . . . inserted in the conjunctiva." *Id.*

Simply stated, the '319 Patent does not anticipate Claim 1 because, among other reasons, the '319 Patent fails to disclose an ocular scleral prosthesis "adapted to expand a portion of a sclera proximate to the scleral pocket or tunnel when [the]... prosthesis is inserted within [the]... scleral pocket or tunnel." The '319 Patent fails to disclose an end portion that is "adapted to rest on a portion of [the]... sclera outside [the]... scleral

pocket or tunnel when [the]... prosthesis is inserted within [the]... scleral pocket or tunnel and to inhibit rotation of [the]... prosthesis within [the]... scleral pocket or tunnel."

In point of fact, the stated purpose of the '319 Patent is, once implanted, is to provide a continuous flow of aqueous humor. The '319 Patent implant does not disclose, teach or suggest a design for an ocular scleral prosthesis as set forth in Claim 1.

Since the above-emphasized limitations, among others, are not disclosed, suggested or even hinted at in the '319 Patent, the '319 Patent does not anticipate Claim 1. Furthermore, dependent Claims 2, 3, 5 and 6, which depend directly or indirectly from independent Claim 1, contain the limitations contained in Claim 1, as well as any intervening claim. Dependent Claims 2, 3, 5 and 6 present patentable subject matter over the '319 Patent as well.

In the Office Action, the Examiner rejected Claims 10, 11, 13-15, 17, 18 and 20 under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. RE 37,390 (hereafter, "the '390 Patent") in view of United States Patent No. 5,370,607 (hereafter, "the '607 Patent"). The Applicant respectfully traverses the Examiner's rejection of Claims 10, 11, 13-15, 17, 18 and 20. The Applicant respectfully directs the Examiner's attention to independent Claim 10, which contain unique and novel limitations:

10. A vision alteration structure, comprising:
at least one prosthesis for insertion into a pocket or tunnel within a sclera for an eye, comprising:
a body having a central portion and at least one end portion integrally formed with and extending from an end of said central portion, said at least one end portion being wider and thinner than said central portion,
said central portion having at least one curved surface for contacting an inner surface of said scleral pocket or tunnel into which said prosthesis is to be implanted,
wherein said prosthesis is adapted to expand a portion of a sclera proximate to said scleral pocket or tunnel when said prosthesis is inserted within said scleral pocket or tunnel. [emphasis added]

The Applicant respectfully asserts that the limitation emphasized in Claim 10 above is not disclosed or suggested, or even hinted at in the '390 and '607 Patents, whether alone or in combination.

The claimed invention provides, a vision alteration structure that comprises at least one prosthesis. The at-least-one prosthesis is for insertion into a pocket or tunnel within the sclera for an eye and comprises a body. The body has a central portion and at least one end portion integrally formed with and extending from an end of said central portion, the at least one end portion being wider and thinner than the central portion. The central portion has at least one curved surface for contacting an inner surface of the scleral pocket or tunnel into which said prosthesis is to be implanted, wherein said prosthesis is adapted

to expand a portion of the sclera proximate to the scleral pocket or tunnel when the prosthesis is inserted within the scleral pocket or tunnel

The exemplary at-least-one end portion (having a width greater than the width of the central body portion) inhibits rotation of the prosthesis about a long axis when the prosthesis is implanted within a scleral pocket or tunnel. The other end of the central body portion may have a blunted end portion including grooves for receiving a edge or lip of an incision forming the scleral tunnel to inhibit the prosthesis from sliding within the scleral tunnel.

Curvature of the bottom surface of the central body portion may be greater than the curvature of the innermost surface of the scleral tunnel so that contact between the scleral and the bottom surface of the prosthesis is primarily with the end portions.

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788

(Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of nonobviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more, the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all

the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2142.

The stated object of the '390 Patent is to provide an implant that is biocompatible with the tissue of the eye and allows fluid to migrate from the anterior chamber into the coarsely woven fibers of the sclera, thus by-passing the obstructed trabecular meshwork but, instead of leaving the body of the eye, exiting into the outer layer of the eyeball, the sclera. The '390 Patent involves:

> substituting a material that is composed of small pores of similar size or larger than a healthy trabecular meshwork in an area almost adjacent to the area of the troubled trabecular meshwork, *i.e.*, close to where the sclera meets the cornea. In this manner, an area of relatively small pores within the implant, is placed within the relatively large pores of the sclera. . . . The [*Smith*] device is adapted to be implanted within the scleral tissue of the eye with at least one edge of the device at an opening of, with no substantial extension into, the anterior chamber adjacent to the area where the sclera makes the transition into the clear cornea of the eye. The pores of the body portion are of such size and quantity as to permit drainage of fluid from the anterior chamber to the scleral tissue without collapse of the anterior chamber. . . . The [*Smith*] implant is shaped to retain its position once it is implanted within the eye and to provide sufficient surface area to accommodate the migration of the aqueous humour in a controlled manner, *i.e.*, enough migration to reduce intra-ocular pressure but not enough to cause collapse of the chamber.

(*See, Smith*, col. 3, lines 26-34, 39-47 and 55-61).

Nowhere does the '390 Patent teach, disclose or even suggest the unique and novel limitations emphasized in above-amended Claim 10; and, more particularly, a prosthesis adapted for insertion into a pocket in the sclera of an eye in the region of the ciliary body and that has a shape prescribed apply force to the pocket or tunnel to cause scleral expansion.

The Applicant respectfully asserts that Claim 10 presents patentable subject matter over the '390 Patent. The '607 Patent is of no assistance to the deficiencies of the '390 Patent. The '607 Patent is directed to a pre-assembled, single-piece device (and related surgical procedure) to surgical implantation in an eye for treating refractory glaucoma by draining aqueous out of the anterior chamber using a tubular shunt depended from a flexible band having a main reservoir (and at least two wings extended in directions opposite one another away from said main reservoir) and an anchoring head each having a tip end and a lock end (with each anchoring head gradually increasing in thickness to form a taper from each tip end to each respective lock end to guide each anchoring head under and past the extraocular muscles of the eye). The device is further defined by a plurality of circumferential markings regularly placed along the tubular shunt for placement

within the anterior chamber according to the size eye of each respective patient, and a ligature integrally formed on the exterior of the main reservoir above the tab to releasably pre-crimp the tubular shunt for restricting aqueous flow immediately after implantation of the device for a sufficient period to prevent hypotony, after which period the ligature can be released to allow for safe flow of aqueous.

Simply stated, there is no reason, stated, suggested or otherwise, to combine the teachings of the '390 Patent and the '607 Patent to arrive at the present invention. Even looking backwards from the combination of these references at the present invention, which is legal impermissible, the Examiner cannot arrive at the present invention.

Claims 11, 13-15, 17, 18 and 20, which depend directly or indirectly from Claim 10, contain all of the limitations of their respective base and intervening claims. This being the case, Claims 11, 13-15, 17, 18 and 20 also present patentable subject matter over the '390 Patent and the '607 Patent, whether alone or in combination.

It is respectfully submitted that the Examiner's rejections stand traversed.

The Applicant denies any statement, position or averment of

the Examiner that is not specifically addressed by the foregoing argument and response. The Applicant reserves the right to submit further arguments in support of its above-stated position, as well as the right to introduce relevant secondary considerations including long-felt but unresolved needs in the industry, failed attempts by others to invent the invention, and the like, should that become necessary.

SUMMARY

The Applicant's attorney appreciates greatly the work the Examiner has done in reading this Application and in attending to the claims. For the reasons given above, the Applicant respectfully requests reconsideration of this Application, and that this Application be passed to issue.

Other than the amount set forth in the check accompanying this Amendment, the Applicant believes that no other fee is do by virtue hereof, however, any fees due by virtue of this Amendment should be charged to Deposit Account No. 50-0208.

If any outstanding issues remain, or if the Examiner has any further suggestions for expediting prosecution of this application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at via

electronic mail at wmunck@davismunck.com.

Respectfully submitted,

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APPENDIX SHOWING CLAIMS WITH MARKINGS

1. A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising:

a central body portion having a first end and a second end, at least one end portion extending from either said first or second end of said central body portion, said at least one end portion having a width greater than said central body portion,

said central body portion having a bottom surface which is curved along a long axis of said prosthesis,

wherein a curvature of said bottom surface is greater than a curvature of an innermost surface of a scleral pocket or tunnel into which said prosthesis is to be implanted,

wherein said prosthesis is adapted to expand a portion of a sclera proximate to the scleral pocket or tunnel when said prosthesis is inserted within said scleral pocket or tunnel, and

wherein said end portion is adapted to rest on a portion of said sclera outside said scleral pocket or tunnel when said prosthesis is inserted within said scleral pocket or tunnel and to inhibit rotation of said prosthesis within said scleral pocket or tunnel.

2. The prosthesis according to claim 1, wherein said at least one end portion has a width greater than a width of said scleral pocket or tunnel into which said prosthesis is to be implanted.

3. The prosthesis according to claim 1, wherein said central body portion tapers steeply from a thickness of said central body portion to a thickness of said at least one end portion within a region where said at least one end portion joins said central body portion.

4. Withdrawn *without prejudice*.

5. The prosthesis according to claim 1, wherein said at least one end portion has a flat bottom surface.

6. The prosthesis according to claim 1, further comprising:

a tapered end portion extending from one of said first or second ends opposite another of said first and second ends from which said at least one end portion extends.

7. Withdrawn *without prejudice*.

8. Withdrawn *without prejudice*.

9. Withdrawn *without prejudice*.

10. A vision alteration structure, comprising:

at least one prosthesis for insertion into a pocket or tunnel within a sclera for an eye, comprising:

a body having a central portion and at least one end portion integrally formed with and extending from an end of said central portion, said at least one end portion being wider and thinner than said central portion,

said central portion having at least one curved surface for contacting an inner surface of said scleral pocket or tunnel into which said prosthesis is to be implanted,

wherein said prosthesis is adapted to expand a portion of a sclera proximate to said scleral pocket or tunnel when said prosthesis is inserted within said scleral pocket or tunnel.

11. The vision alteration structure according to claim 10, wherein said at least one end portion rests on a surface of said sclera outside said scleral pocket or tunnel when said prosthesis is inserted within said scleral pocket or tunnel.

12. Withdrawn *without prejudice*.

13. The vision alteration structure according to claim 10, wherein said at least one end portion is wider than said scleral pocket or tunnel when said prosthesis is inserted within said scleral tunnel.

14. The vision alteration structure according to claim 13, wherein said at least one end portion is sized to pass through said scleral tunnel as said prosthesis is inserted into said scleral tunnel.

15. The vision alteration structure according to claim 10, wherein a portion of said prosthesis including a region where said central portion joins said at least one end portion tapers steeply from a thickness of said central portion to a smaller thickness of said at least one end portion.

16. Withdrawn *without prejudice*.

17. The vision alteration structure according to claim 10, wherein said at least one end portion has a bottom surface including a flat region.

18. The vision alteration structure according to claim 10, further comprising:

a tapered end portion integrally formed with and extending from an end of said central portion opposite said at least one end portion.

19. Withdrawn *without prejudice*.

20. The vision alteration structure according to claim 10, further comprising:

a plurality of additional prostheses each having a structure of said at least one prosthesis, said plurality of additional prostheses and said at least one prosthesis positioned within equidistantly spaced scleral pockets or tunnels around a cornea of an eye.